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09/783,763	02/14/2001	Norbert Windhab	260/095	2275
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O'MELVENY & MEYERS 114 PACIFICA, SUITE 100 IRVINE, CA 92618			EXAMINER WESSENDORF, TERESA D	
			ART UNIT 1639	PAPER NUMBER

DATE MAILED: 01/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/783,763

**Applicant(s)**

WINDHAB ET AL.

**Examiner**

T. D. Wessendorf

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-98,100-111 and 113-116 is/are pending in the application.
- 4a) Of the above claim(s) 1-95,97,100-102 and 108-110 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 96,98,103-107,111 and 113-116 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_ 6) ☐ Other: \_\_\_\_

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**DETAILED ACTION**

***Status of Claims***

Claims 1-98, 100-111 and 113-116 are pending in the application.

Claims 1-95, 97, 100-102 and 108-110 are withdrawn from consideration as being drawn to non-elected invention.

Claims 99 and 112 have been cancelled.

Claims 96, 98, 103-107, 111 and 113-116 are under examination.

***Specification***

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required:

In view of the amendments to the claims this objection has been overcome.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 96, 98, 103-107 and 111, 113-116 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a p-RNA as the pairing component; an microelectronic array and Ig, does not reasonably provide enablement for the broadly recited pairing complexes, array and Ig derivatives or fragments. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims for the reasons set forth in the last Office action.

***Response to Arguments***

Applicants state that claim 96 has been amended to specify a pairing component comprising p-RNA.

In response, the pairing component is but one of the numerous undefined variables of the broad claimed complex. Accordingly, the rejection is maintained essentially for the same reasons set forth in the last action. [It is suggested applicants limit the claims to the species, as elected].

Claims 96, 98, 103-107 and 111, 113-116 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a

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way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification fails to provide a description of an array of microlocations. The relevant sections cited by applicants e.g., page 10, line 13 up to page 11, line 9 and etc. do not recite for an array of microlocations. Rather, the sections describe an active electronic matrix. It is suggested that applicants use the terminologies that are present in the specification to provide antecedent support for the claim and consistency therewith.

***Claim Rejections - 35 USC § 112, second paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 96, 98, 103-107 and 111, 113-116 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for reasons advanced in the last Office action.

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In view of the amendments and cancellation of some claims the rejections under paragraphs A-E under this statute has been overcome.

However, the claims, as amended, are rejected as follows:

1. Claim 96 used of the term "complex" appears to go against the conventional way of claiming a complex i.e., without an array and the analyte, but only the components present in the array since an analyte would be a complex in and of itself. The term "adapted" is unclear, within the claimed context, e.g., the means or modifications done to the complementary pairing component to enable hybridization.

2. Claim 115 is confusing as whether the pairing component is "adapted" to the complementary pairing component or vice versa as recited in claim 96. It is not clear as to the differentiating features or characteristics of the relative terms "first" and "second" for each of the different components, especially in the absence of positive recitation in the specification as to reference of these relative terms.

In view of the amendments to e.g., claims 96 the rejection of under U.S.C. 102(e) as being anticipated by Cubicciotti (U.S. 6,287,765) has been obviated. However, the newly amended claims are rejected as follows:

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***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 96, 98, 103-104, 106-107, 111 and 113-116 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miculka et al (U.s. 6,506,896 equivalent to WO 99/15541).

Miculka discloses at col. 3, lines 41 up to col. 5, line 32, an array comprising a pRNA in the form of a conjugate comprising a pRNA/RNA and a biomolecule for the production of an electronic component, in particular in the form of a diagnostic. Conjugates are covalently bonded hybrids of p-NAs and other biomolecules, preferably a peptide, protein or a nucleic acid, for example an antibody or a functional moiety thereof or a DNA and/or RNA occurring in its natural form. Functional moieties of antibodies are, for example, Fv fragments, single-chain Fv fragments or Fab fragments. Biomolecule is a naturally occurring

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substance or a substance derived from a naturally occurring substance. In a preferred embodiment, they are in this case p-RNA/DNA or p-RNA/RNA conjugates. Conjugates are preferably used when the functions "sequence recognition" and "non-covalent bonding" must be realized in a molecule, since the conjugates according to the invention contain two pairing systems which are orthogonal to one another. p-NAs and in particular the p-RNAs form stable duplexes with one another and in general do not pair with the DNAs and RNAs occurring in their natural form. This property makes p-NAs preferred pairing systems. The term conjugate is also understood as meaning so-called arrays. Arrays are arrangements of immobilized recognition species which, especially in analysis and diagnosis, play an important role in the simultaneous determination of analytes. Examples are peptide arrays (Fodor et al., Nature 1993, 364, 555) and nucleic acid arrays (Southern et al. Genomics 1992, 13, 1008; Heller, U.S. Pat. No. 5,632,957). A higher flexibility of these arrays can be achieved by binding the recognition species to coding oligonucleotides and the associated, complementary strands to certain positions on a solid carrier. By applying the coded recognition species to the "anti-coded" solid carrier and adjustment of hybridization conditions, the recognition species are non-covalently bonded to the desired positions. As a result,



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various types of recognition species, such as, for example, DNA sections, antibodies, can only be arranged simultaneously on a solid carrier by use of hybridization conditions (see FIG. 3). The prerequisite for this, however, are codons and anticodons which are extremely strong and selective--in order to keep the coding sections as short as possible--and do not interfere with natural nucleic acid necessary. p-NAs, preferably p-RNAs, are particularly advantageously suitable for this. The present invention therefore also relates to the use pentopyranosylnucleic acids, preferably ribopyranosylnucleic acids for encoding recognition species, preferably natural DNA or RNA strands or proteins, in particular antibodies or functional moieties of antibodies. These can then be hybridized with the appropriate codons on a solid carrier according to FIG. 3. Thus arrays which are novel and diagnostically useful can always be built up in the desired positions on a solid carrier which is equipped with codons in the form of an array only by adjustment of hybridization conditions using combinations of recognition species which are always novel. If the analyte, for example a biological sample such as serum or the like, is then applied, the species to be detected are bonded to the array in a certain pattern which is then recorded indirectly (e.g. by fluorescence labelling of the recognition species) or directly

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(e.g. by impedance measurement at the linkage point of the codon). The hybridization is then eliminated by suitable conditions so that again only the carrier having the codons remains. This is then again loaded with other recognition species and is used, for example, for the same analyte for the determination of another sample. The always-new arrangement of recognition species in the array format and the use of p-NAs as pairing systems are particularly advantageous compared with other systems. Further, this also relates to an electronic component in particular in the form of a diagnostic, comprising an above-described pentopyranosylnucleoside or a pentopyranosylnucleoside in the form of a conjugate in which a pentopyranosylnucleoside or a pentopyranosylnucleic acid is combined with a biomolecule, as described in detail above. Accordingly, the conjugate of Miculka comprising of similar, if not the same, components as the claimed complex renders the claimed complex *prima facie* obvious, albeit, the instant invention is termed a complex. However, it is considered that the conjugate of Miculka forms also a complex especially in view of Miculka's disclosure that the conjugate is formed into an array.

Claim 105 is rejected under 35 U.S.C. 103(a) as being unpatentable over Miculka in view of Cubicciotti et al.

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Miculka is discussed above. Miculka does not disclose the non-covalent interaction via biotin-streptavidin. However, Cubicciotti discloses the conventionality of interaction via biotin-streptavidin. Miculka discloses that biotin/streptavidin and biotin/avidin are different specific binding pairs because the two specific binding pairs comprise three distinguishable chemical identities (i.e., biotin, streptavidin and avidin). The difference in chemical identity between, e.g., streptavidin vs. avidin or avidin-peroxidase vs. avidin-glucose oxidase is not accompanied by a sufficient difference in biotin-binding specificity to enable positional control of specific binding pairs. In other words, a defined sequence segment which is biotinylated at each of two defined nucleotide positions does not provide the requisite chemical specificity to attach avidin and streptavidin, on the one hand, or two different avidin-effector conjugates, on the other hand, in an ordered and reproducible positional relationship to one another. Nucleotide-based templates and multimolecular devices disclosed herein, however, are capable of positioning different specific binding pairs having similar and even indistinguishable binding specificities. When used in reference to MOLECULAR MACHINES or multivalent molecular structures capable of specifically recognizing a surface feature, "different specific binding

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pairs" means "different specific recognition pairs," i.e., two specific recognition pairs whose four members comprise at least three different chemical identities, wherein the members may be capable of specific shape recognition. Accordingly, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the biotin-avidin pair in the complex of Miculka since this is conventionally done in the art as taught by Cubicciotti. This is especially true for a multivalent structures as taught by Cubicciotti, above.

#### ***Allowable Subject Matter***

In view of the amendments to the claims and the application of the new prior art to the claims, as amended, the indicated allowability of claims 99 and 107 has been withdrawn.

#### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS

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of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

This application contains claims 1-95, 97, 100-102 and 108-110 drawn to non-elected invention. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **T. D. Wessendorf** whose telephone number is (703) 308-3967. The examiner can normally be reached on Flexitime.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (703) 306-3217. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-7924 for regular communications and (703) 308-7924 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

*T.D. Wessendorf*

T. D. Wessendorf  
Primary Examiner  
Art Unit 1639

tdw  
January 21, 2004